

1654 # 17 PATENT 6/17/03

Attorney Docket No.:

8820-3

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

Patent application of

Alvin H. Schmaier

Serial No.:

09/402,732

Filed:

December 01, 1999

For:

BRADYKININ ANALOGS AS

SELECTIVE INHIBITORS OF CELL

**ACTIVATION** 

Group Art Unit:

1654

Examiner:

Gupta, Anish

**RECEIVED** 

**DEC 1 1** 2002

**TECH CENTER 1600/2900** 

# Response to Restriction Requirement

Commissioner for Patents U.S. Patent and Trademark Office Washington, D.C. 20231

Sir:

This paper is responsive to the Restriction Requirement mailed November 5, 2002 (Paper No. 16). This paper is being submitted within the one-month shortened statutory period, and therefore no fee is believed due. If a fee is due, please charge deposit account no. 50-0573.

#### CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.

BY	Wee Haticchia	
DATE:	12/3/02	_
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#### Remarks

Claims 1-28 are pending in the application, and are subject to a restriction requirement.

## Response to Restriction Requirement

Applicants elect the claims of Group II (claims 1-25), drawn to branched peptides, classified in class 514, subclass 12+, with traverse, for the reasons outlined below.

The Examiner has also requested that if election is made to the claims of Group II, then a species election must be made for the compounds of the formula L- $(X_1$ -Arg-Pro-Pro- $X_2)_n$ . Applicants hereby elect the species RPPMAP-4, as disclosed on page 32, lines 3-21.

The Examiner alleges at page 2 in the Detailed Action that the compounds of Groups I and II are distinct from each other, even though there may be overlap between class and subclass, because they are structurally distinct from one another. Particularly, it is the opinion of the Examiner that because the compounds of Group I (claims 1-7, 10, 11-20, 23, and 24) do not use the linker L, there is structural distinction between the groups. Applicants respectfully disagree.

Restriction is proper only if the pending claims represent independent or distinct inventions, *and* there is a serious burden in searching and examining the entire application. MPEP §803. Here, Examiner cannot show that Groups I and II represent independent or distinct inventions, or that there is a serious burden on searching and examining these claim groups in one application.

Applicants respectfully submit that the restriction is improper because the claims are directed to related subject matter and are not independent and distinct. Applicants traverse based on the fact that all of the claims of Groups I and II are drawn to core sequences comprising the formula  $(X_1$ -Arg-Pro-Pro- $X_2$ )<sub>n</sub>. Furthermore, Applicants note that the Examiner has classified each group in the same class and subclass. Thus, to the extent discussed below, the restriction requirement is improper and should be withdrawn.

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Claim Groups I and II Are Not Distinct

According to MPEP 802,

"The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, . . . "

Contrary to the Examiner's assertion, the subject matter of the claims is not capable of separate manufacture, use or sale. All of the claims of Groups I and II require the presence or use of  $(X_1-Arg-Pro-Pro-X_2)_n$  or depend from such a claim.

Inventions are distinct only if they are 1) classified separately, 2) have acquired separate status in the art when classified together, or 3) require a different field of search (i.e., it is necessary to search for one invention in places where no pertinent art exists for the others). MPEP § 808.02. Here, the Examiner asserts that Groups I and II are distinct because the linker L is used in Group II, even though the basic core sequence " $(X_1-Arg-Pro-Pro-X_2)_n$ " is the same for both groups.

With regard to Groups I and II, the groups are not classified separately under §808.02(A), as Examiner has put each group in the identical class (514). Moreover, both groups are classified in subclass 12+.

The groups do not represent "separate inventive effort" under §808.02(B), as they all relate to the same basic methods for using the claimed compounds to inhibit platelet or cell activation and function or to pharmaceutical compositions.

Finally, Groups I and II do not require a different field of search under  $\S 808.02(C)$ , because both have the identical classification and subclassification. Applicant also notes that in performing a patentability search for a peptide comprising  $(X_1\text{-Arg-Pro-Pro-}X_2)_n$ , whether or not there is an L linker, in the context of the present claims, the Examiner will necessarily uncover the prior art pertaining to the claims of both groups. Therefore, no undue burden is placed on the Examiner to search for both types of compounds at one time and it is unlikely that a search of one claim group would reveal no art that is pertinent to the other.

Therefore, Groups I and II fail to satisfy any of the criteria set forth in MPEP §808.02, and thus are not distinct.

Restriction Is Improper for Groups I and II

As shown above, Groups I and II are not independent and are not distinct. According to MPEP §§806 and 806.05, if inventions are related but not distinct, restriction is "never proper."

There Is No Serious Burden In Searching Claim Groups I and II

Even assuming *arguendo* that Groups I and II represent independent or distinct inventions, restriction is not proper because there is no serious burden on Examiner in searching all claim groups.

According to MPEP §803 (emphasis added), "a serious burden . . . may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP §808.02." Examiner has given no explanation at all to support a contention that searching Groups I and II together poses a serious burden. The Examiner merely states at page 2, item 2, of the Detailed Action that "The use of the linker gives the compounds of Group II structural distinction over Group I and thus render them patentably distinct." Applicants respectfully submit, as discussed above, that there can be no serious burden in searching Groups I and II together because the compounds of the two groups share the same core sequence, are used for the same purpose, and are classified in the same class and subclass.

### Conclusion

Claim Groups I and II represent non-distinct inventions that do not present a serious search burden for Examiner. Withdrawal of the restriction requirement with respect to Groups I and II, is therefore proper. In light of the election of Group II above, Applicants respectfully request withdrawal of the restriction requirement between Groups I and II and that the claims of Groups I and II be recombined and examined in the present application.

Applicants remind Examiner that MPEP §803 places the burden squarely on the examiner to "provide reasons and/or examples to support conclusions" presented in a restriction requirement. See also MPEP §808.02(B). Thus, if Examiner maintains any or all of the present restriction requirement, Applicants respectfully request that Examiner clearly articulate reasons and/or provide examples and evidence in support of his position.

Applicants believe this response to be fully responsive to the outstanding Restriction Requirement and request prosecution on the merits.

Respectfully submitted,

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